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09/978,309	10/15/2001	Tony Cruz	033352-010	4565

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/30/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,309

Applicant(s)

CRUZ ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application:
- 4a) Of the above claim(s) 7-9 and 15-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 & 10-12
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants' preliminary amendment filed 22 January 2002 (Paper No. 10) as to amendment claims 1-2, 5, 7, 15, 19, 23-24, 28-29 and 34, and applicants' petition for extension of time of one month have been entered.

Election/Restrictions

The current Applicant's election of Group I, claims 1-6 and 10-14 ad SEQ ID NO:74 with traverse filed 7 April 2003 (Paper No. 23) is acknowledged. The traversal is on the ground that searching all the sequences set forth in the elected claims presents no serious burden to the Examiner; thus, applicants assert that the claims 1-6 and 10-14 together with claimed amino acid sequences (SEQ ID NOs: 26, 81 and 73-78) should be examined. The applicants' argument is unpersuasive because the sequences are structurally distinct or different from one another, e.g., (i) SEQ ID NO:73 has 333 residues while SEQ ID NO:74 (elected) possesses only 242 residues, and (ii) the sequences of SEQ ID NOs: 73 and 74 are distinct from each other with respect to their N- and C-terminal regions, e.g., positions 16 and 32 are different amino acid residues in the two sequences. In addition, applicants assert that the amino acid sequences of SEQ ID NOs: 26, 81 and 73-78 are species. It should be noted that the restriction requirement mailed 15 May 2003 is NOT species election but additional election since each sequence is directed to independent invention. Thus, the amino acid sequences are patentably distinct and search for all the sequences would be a burden to the Examiner. The requirement is therefore still deemed proper and is therefore made FINAL.

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Claims 7-9 and 15-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, elected claims 1-6 and 10-14 are under examination to the extent that they are drawn to the elected invention.

IDS

Please note that Applicants' submission of IDS filed 25 February 2002 (Paper No. 7) is incomplete since it contains no legible copies of each U.S. and foreign patent and each publication or that portion, which caused it to be listed as cited in the list of the submitted IDS. Also, Applicants' submission of IDS filed 17 June 2002 (Paper No. 10), IDS filed 19 April 2002 (Paper No. 11) and IDS filed 16 April 2002 (Paper No. 12) are incomplete are also incomplete for the same reason stated above. Thus, it fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C (1). Yet, examiner has reviewed all US patent documents of IDS (Paper No. 10), EP0721012 and Chao, et al. reference of IDS (Paper No. 12), and WO 9738098 of IDS (Paper No. 7), listed in the IDS documents by applicants and herewith provided one of each copy of the patent documents (note that Chao et al. should be Wang et al. because Chao is cited as first name instead of last name for the same reference).

Objection to Specification/Claims

The disclosure is objected to because of the following informalities:

- (1) In page 7, line 20, "SEQ ID Nos. 14-20" should be changed to "SEQ ID NOs: 14-20".

The same change should be made throughout the specification.

- (2) In page 9, line 4, "aa423-432" should be changed to "amino acid residues 423-432".

- (3) In page 20, line 28 the upper case of "TO" should be changed to low case one.

- (4) In page 20, line 18, "SEQ. ID NO: 1-10" should be changed to "SEQ ID NO: 1-10".

The same change should be made throughout the specification.

- (5) In page 39, line 19, "MMTV", "LTR" and "PSV" should be spelled out in full for the first instance of use. See also page 80, line 9, "MAP"; page 83, line 18, "ERK"; page 84, line 19, "MAPK", and line 21, "SDS-PAGE", and line 24, "TBS-T"; page 86, line 19, "DEPC"; page 89, line 7, "PDGF" and line 12, line ERK2"; page 90, line 14, "TNF- α "; page 94, line 8, "ELISA"; page 105, line 8, "RIPA", page 111, line 12, "ABC", line 14, "DAB" and line 24, "RA"; page 115, line 18, "RT-PCR"; page 131, line 22, "HA"; page 136, line 18, "CaP"; and page 138, line 16, "IDDM".

- (6) In page 52, line 12, "73 kd" should be changed to "73 KD".

- (7) In page 54, line 9, "Sequence ID No. 70" should be changed to "SEQ ID NO:70"; the same change should be made throughout the specification.

- (8) In page 102, line 19, "423-432 AA" should be changed to "423-432 amino acid residues".

Corresponding correction is required.

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Claim Rejections - 35 USC § 101

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1, as written, does not sufficiently distinguish over other polypeptide, proteins and enzymes, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, *e.g.*, by insertion of "recombinantly produced or isolated" (see pages 32-33 of the specification). See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 and 5 recites non-elected sequences which render the claims indefinite. The dependent claims are also rejected.

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Claim 10 sets forth "an antigen for the antibody of claim 7". The antibody is a subject matter being drawn to non-elected invention, which render claim indefinite. Thus, re-writing the claim is advised in order to eliminate the subject matters which have been withdrawn from consideration in this Office Action. See also claim 14. The dependent claims are also rejected.

Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 and 10-14 are rejected under 35 U.S.C. 103(a) as being obvious over Turley, E. A. et al. (WO 9738098) (A) taken with Charo, I. F. et al. (US Pat. No. 5707815).

Turley et al. (A) teach a polypeptide sequence comprising the sequence of SEQ ID NO:74 of the instant application (see the amino acid sequence of human RHAMM (receptor hyaluronic acid mediated motility) at Turley et al. (A), page 46, Table 3. In the above references, residues 443 to 684 of Turley sequence are identical to residues 1-242 of the full-length SEQ ID

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NO:74 of the instant application except that position 154 isoleucine of the instant application is leucine for the sequence of Turley et al. Charo et al. teach that conservative replacement of leucine to isoleucine does not have major effect on the folding structure and activity of the subject polypeptide (see column 4, lines 10-15). Thus, the Turley et al. in view of Charo et al. teaching is obvious variations over the composition of application claims 1 and 10-14.

Claims 10-14 as written set forth the same composition as that of claims 2-10 wherein the RHAMM polypeptide is an antigen for the antibody irrespective of the preamble "vaccine" that has not patentable input on the claimed composition thereof. Please note that the current invention is directed to the composition not a method of use the composition thereof, and the intended use (e.g., treating inflammatory neurological disorder) has no patentable weight *per se* associated with the claimed composition which structure and biological activity will not be altered due to the use of the RHAMM polypeptide for inflammatory neurological disorder state, e.g., multiple sclerosis.

One of ordinary skill in the art would have been motivated to combine the above references as one is inextricably led to the Turley et al. (A) in view of Charo et al. teaching regarding conservative substitution of isoleucine with leucine to arrive at the claim invention.

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being obvious over Turley, E. A. et al. (WO 9738098) (A) taken with Charo, I. F. et al. (US Pat. No. 5707815) as applied to claim 1 above in view of Turley, E. A. et al. (EP 0721012) (B).

Turley et al. in view of Charo et al. teach the obvious variation of RHAMM polypeptide of SEQ ID NO:74 of the current application (see the above statement). Also, Turley et al. (A)

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teach the RHAMM polypeptide being used in protein therapy for treating a disease state (see pages 22-23). Yet, Turley does not explicitly teach a pharmaceutical composition comprising the claimed RHAMM polypeptide.

Turley, E. V et al. (B) teach a pharmaceutical composition (see page 31, lines 1-17) comprising the isolated human RH polypeptide for treating any disorder arising from unwanted or excessive stimulation of cell-associated RHAMM (see page 31, lines 16-17). Thus, Turley et al. (A) teaching in view of Turley et al. (B) is obvious over claims 2-6 of the instant application.

One of ordinary skill in the art would have combined the teachings of the above references because Turley et al. (B) teaches the pharmaceutical composition comprising the RHAMM polypeptide for treating a disorder state associated with abnormally regulated RHAMM. When combined, the skilled artisan would have successfully arrived the current invention the claimed polypeptide, i.e., pharmaceutical composition comprising the RHAMM polypeptide thereof. Thus, the claimed invention was *prima facie* obvious to make and use at the time it was made.

Provisional Rejection - Obviousness Type Double Patenting

Claim 1 of this application conflict with claims 34 of Application No. 09685010. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of double patenting over claims 34 of copending Application No. 09685010. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claim 34 of Application 09685010 sets forth a polypeptide comprising all or portion of domains of RHAMM; the claim language as written encompasses the SEQ ID NO:74 of the instant application since SEQ ID NO:74 is a portion of full-length RHAMM protein. Thus, the instant application and copending application claim is obvious variation.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, PhD.

July 21, 2002

Karen Cochrane Carlson

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER